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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,182	09/12/2003	Megan Tran	AM100212	8285
23377	7590	09/20/2004	(CON)/WYNC-0331	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103			EXAMINER HUANG, EVELYN MEI	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/661,182

Applicant(s)

TRAN ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 19-33 are pending. Claims 1-18 have been canceled according to the preliminary amendment filed on 9-12-2003.

Claim Rejections - 35 USC § 112

2. The rejection for claims 19-33 under 35 U.S.C. 112, second paragraph, is withdrawn upon reconsideration in view of Applicant's remarks.

Claim Rejections - 35 USC § 112(1)

3. The rejection for Claims 19-33 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record.

Applicant maintains that the procedures for the 5-HT transporter binding assays, 5-HT_{1A} receptor binding assays, and the assay for the assessment of the antagonist activity, are found on pages 9-10 of the specification. Data for representative compounds on page 10 of the specification show that the inventive compounds are combined serotonin reuptake inhibitors (SSRI) and 5HT_{1A} antagonists, and are expected to be useful for treatment of diseases commonly treated with SSRI, such as bulimia nervosa, anorexia nervosa, binge-eating disorders and sexual dysfunction, as described in Lee et al. (Formulary 2002, 37:312-319).

On the contrary, Lee actually concludes that only bulimia nervosa has been shown to be effectively treated with SSRIs. There is little evidence for the use of SSRIs in alcohol dependence, anorexia nervosa, or binge-eating disorders. While SSRIs may appear to be beneficial in treating premature ejaculation, they are associated with the undesirable orgasm delay (page 318, last paragraph). One of ordinary skill in the art therefore would have no basis to use SSRIs to treat erectile dysfunction, which is embraced by the instant 'sexual dysfunction', nor would one of ordinary skill in the art be able to use the SSRIs to treat hyperphagia, which is embraced by the instant 'eating disorders'. Indeed, at the time of the invention, the nexus

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between the antagonism of 5HT_{1A} receptor and inhibition of serotonin reuptake and the treatment of obesity, eating disorders, vasomotor flushing, cocaine addiction, alcohol addiction or sexual dysfunction has not been fully established.

Furthermore, in view of the high degree of unpredictability is well recognized in the 5-HT receptor ligand art and the SSRI art, wherein a slight change in the structure of the compound would drastically alter its affinity and selectivity (Wijngaarden, Recl. Trav. Chim. Pays-Bas, 1993, 112:126-130, pages 129-130, Fig. 6, Fig. 7, Fig. 8), one of ordinary skill in the art would have not basis to extrapolate the results of the known SSRIs (such as fluoxetine, paroxetine, sertraline, fluvoxamine, or citalopram) to the inventive compound, which is structurally unrelated to any of these SSRIs.

Applicant contends that a lack of working examples with respect to methods of treating obesity, eating disorders, vasomotor flushing, cocaine addiction, alcohol addiction or sexual dysfunction does not automatically make the patent non-enabling. 35 U.S.C. 112 first paragraph does not demand a 'working example'.

The rejection, however, is not based solely on the lack of working examples. The examiner agrees that a working example is not required to satisfy the enablement requirement, and some experimentation is permitted and every claimed embodiment need not be shown to possess the asserted activity. However, there should be a showing commensurate in scope with the claims. In the instant SSRI and 5HT_{1A} antagonist art, where there is a high degree of unpredictability exists, the required disclosure will be greater than for the disclosure of an invention involving a predictable factor such as a mechanical or electrical element. In re Vaeck, 20 USPQ 2d 1438.

In conclusion, since the instant 'eating disorders', 'sexual dysfunction' etc. are general classes of disorders embracing opposing and conflicting conditions, it is impossible to use a single SSRI/5HT_{1A} receptor antagonist compound of the instant to treat all these contradictory conditions. In view of the state of the art, the high degree of unpredictability of the art, the limited working examples, the scope of the claims does not commensurate with that of the objective enablement. Insufficient teaching and guidance have not been provided in the specification to enable one of ordinary skill in the art to make and use the invention as claimed without undue experimentation.

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Double Patenting

4. The timely filed terminal disclaimer has obviated the obviousness-type double patenting rejection over claims 14-17 of U.S. Patent No. 6656950.

Conclusion

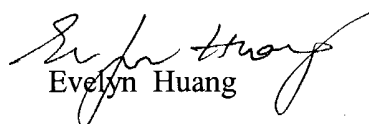
5. No claims are allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

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